

Europäisches Patentamt
European Patent Office
Office européen des brevets



(11) **EP 1 072 275 A1**

(12) **EUROPEAN PATENT APPLICATION**

(43) Date of publication:
31.01.2001 Bulletin 2001/05

(51) Int. Cl.⁷: **A61L 27/16**

(21) Application number: **00202677.1**

(22) Date of filing: **26.07.2000**

(84) Designated Contracting States:
**AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU
MC NL PT SE**
Designated Extension States:
AL LT LV MK RO SI

(72) Inventor: **Rohr, William M.D.**
Marshfield, MA 02050 (US)

(74) Representative: **Mays, Julie**
Bristol-Myers Squibb Company,
Patent Department,
Swakeleys House,
Milton Road
Ickenham, Uxbridge UB10 8NS (GB)

(30) Priority: **29.07.1999 US 361210**

(71) Applicant:
Bristol-Myers Squibb Company
New York, N.Y. 10154 (US)

(54) **Method of manufacturing an articulating bearing surface for an orthopaedic implant**

(57) A method of manufacturing an articulating bearing surface for use in an orthopaedic implant uses a supply of ultra-high molecular weight polyethylene particles which are irradiated with sufficient radiation

energy to crosslink at least a portion of the ultra-high molecular weight polyethylene. The irradiated particles are then formed into an orthopaedic bearing surface.

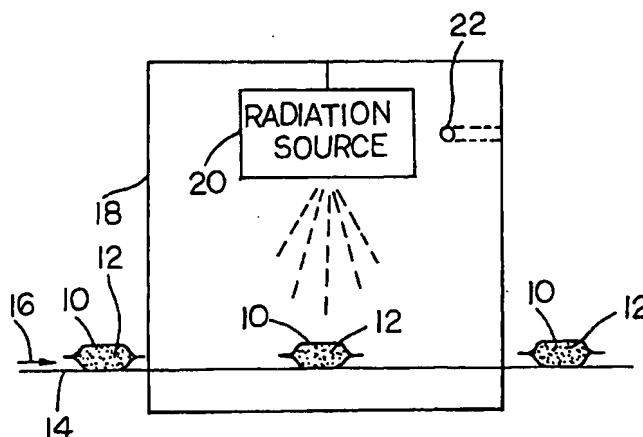


FIG. 1

EP 1 072 275 A1

Description**BACKGROUND OF THE INVENTION****1. Field of the Invention.**

[0001] The present invention relates to orthopaedic implants, and, more particularly, to articulating bearing surfaces for orthopaedic implants.

2. Description of the Related Art.

[0002] Orthopaedic implants used to reconstruct a joint of a patient typically include two implant halves with each implant half defining an articulating bearing surface. For example, an orthopaedic knee implant includes a proximal component which is placed within the femur and a distal component which is placed within the tibia. The proximal component typically includes a metallic articulating bearing surface which pivots on a non-metallic articulating bearing surface defined by the tibial knee component. The non-metallic bearing surface may be formed from a block of ultra-high molecular weight polyethylene (UHMWPE) which is machined to define the articulating bearing surface. The non-metallic bearing surface is attached to and carried by a tibial tray, which in turn is affixed to a stem inserted within the intramedullary canal (IM) of the tibia.

[0003] It is known to irradiate a bearing surface constructed from UHMWPE to crosslink the plastic material and improve the wear properties. The bearing surface is formed to a final shape and the entire bearing surface is irradiated. The penetration of the radiation depends upon factors such as the radiation energy, shape of the bearing surface, etc.

SUMMARY OF THE INVENTION

[0004] The present invention provides a method of manufacturing an articulating bearing surface for use in an orthopaedic implant, wherein UHMWPE particles such as powder or flakes are irradiated prior to being shaped into the bearing surface.

[0005] The invention comprises, in one form thereof, a method of manufacturing an articulating bearing surface for use in an orthopaedic implant. A supply of UHMWPE particles are irradiated with sufficient radiation energy to crosslink at least a portion of the UHMWPE. The irradiated particles are then formed into an orthopaedic bearing surface.

[0006] An advantage of the present invention is that irradiation of the UHMWPE can be better controlled.

[0007] Another advantage is that crosslinking of the UHMWPE is accomplished without consideration of the geometric configuration of the articulating bearing surface.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] The above-mentioned and other features and advantages of this invention, and the manner of attaining them, will become more apparent and the invention will be better understood by reference to the following description of an embodiment of the invention taken in conjunction with the accompanying drawings, wherein:

Fig. 1 is a schematic view of an apparatus utilized in an embodiment of the method of the present invention for crosslinking UHMWPE used to make an articulating bearing surface;

Fig. 2 is a plan view of a compression mold and heated platen assembly used to form the crosslinked UHMWPE into an articulating bearing surface; and

Fig. 3 is a perspective view of an articulating bearing surface formed using the apparatus of Fig. 1 and the compression mold of Fig. 2, shown in association with a tibial tray.

[0009] Corresponding reference characters indicate corresponding parts throughout the several views. The exemplification set out herein illustrates one preferred embodiment of the invention, in one form, and such exemplification is not to be construed as limiting the scope of the invention in any manner.

DETAILED DESCRIPTION OF THE INVENTION

[0010] Referring now to the drawings, an embodiment of the method of the present invention for forming an orthopaedic articulating bearing surface of the present invention will be described.

[0011] Packets 10 include a supply of UHMWPE particles 12 such as powder and/or flakes. Packets 10 are formed from a radiolucent material such as plastic which allows radiation energy to impinge upon particles 12 therein. Packets 12 may be sealed using any suitable technique, such as heat or ultrasonic welding. Particles 12 may have a size and shape which is suitable for any orthopaedic application utilizing an articulating bearing surface. For example, particles 12 may have a size which is between approximately 50 and 200 microns.

[0012] Packets 10 are preferably sized to hold an amount of UHMWPE particles 12 which is sufficient to form a desired articulating bearing surface. That is, each packet 10 preferably holds an amount corresponding to a single charge of a compression mold, as will be described hereinafter.

[0013] Packets 10 are carried by a conveyor belt 14 which moves in a traveling direction 16. Each packet 10 is carried to an interior of an irradiation apparatus 18, including a radiation source 20 and a gas port 22. Gas port 22 is used for reducing an amount of oxygen which is present within irradiating apparatus 18 during irradiation.

tion of packets 10 with radiation source 20. For example, gas port 22 may be used for transporting an inert gas such as nitrogen or argon into an interior of irradiating apparatus 18. A reduced oxygen atmosphere within irradiating apparatus 18 inhibits oxidation of particles 12 within packets 10. Alternatively, gas port 22 may be utilized to draw a vacuum on the interior of irradiating apparatus 18 to reduce the oxygen atmosphere therein. If the material from which packet 10 is constructed is not gas permeable, it may also be possible to load the interior of each packet 10 with an inert gas around particles 12, thereby eliminating the need for reducing the oxygen atmosphere within irradiating apparatus 18.

[0014] Radiation source 20 transmits radiation energy which impinges upon particles 12 within packet 10 disposed within irradiating apparatus 18. Radiation source 20 irradiates particles 12 within packet 10 with a sufficient amount of radiation energy to crosslink at least a portion of the UHMWPE from which particles 12 are constructed. Dependent upon the amount of radiation energy used during the crosslinking process, the penetration depth of the radiation energy into particles 12 within packet 10 varies. Preferably enough radiation energy is used to crosslink substantially all of particles 12 within packet 10. The radiation energy preferably is in the form of gamma ray or X-ray radiation, but may also be in the form of ultra-violet radiation, or a radiation beam such as a neutron particle beam, proton particle beam or electron particle beam. In the embodiment shown, the UHMWPE particles 12 within packet 10 are crosslinked using a 10 MeV electron beam providing a total radiation dose level of between approximately 25 and 500 KGy preferably between 100 and 250 KGy, and more preferably between 140 and 180 KGy.

[0015] After a packet 10 disposed within irradiating apparatus 18 is crosslinked using radiation energy from radiation source 20, conveyor belt 14 moves the crosslinked packet 10 out of irradiating apparatus 18 and another packet 10 is moved into irradiating apparatus 18 for crosslinking. The crosslinking of the UHMWPE particles 12 within each packet 10 therefore occurs in a batch manner. It may also be possible to crosslink UHMWPE particles 12 in a continuous manner if particles 12 are not disposed within packets, but rather are carried in a continuous manner in a thin layer on conveyor belt 14 through irradiating apparatus 18. The radiation energy and the travel speed of conveyor belt 14 can be easily matched to provide effective crosslinking of the UHMWPE particles 12 if a continuous process is utilized.

[0016] After UHMWPE particles 12 are crosslinked using radiation energy, the particles 12 are molded to form an articular surface. The particles 12 may be emptied from the packets 10 or molded while still in the packets. The particles, or particles and packets, are placed within a compression mold 24 having two mold halves 26 and 28 which define a mold cavity 30 therebetween. The portion of mold cavity 30 defined by mold

half 26 includes a complimentary articulating bearing surface 33 against which particles 12 are pressed to define an articulating bearing surface 33 (Fig. 3). A gas port 34 is used to reduce the amount of oxygen within mold cavity 30. Reducing the amount of oxygen within mold cavity 30 during the manufacturing process inhibits oxidation of the UHMWPE particles 12. The oxygen within mold cavity 30 may be reduced by applying a vacuum pressure to mold cavity 30 using a vacuum source (not shown) attached to gas port 34 disposed in communication with mold cavity 30. Alternatively, an inert gas such as nitrogen or argon may be introduced into mold cavity 30 through gas port 34.

[0017] Mold halves 26 and 28 are assembled together and placed between platens 36 which provide the dual functionality of pressing mold halves 26 and 28 together (indicated by lines 38), as well as heating mold halves 26 and 28 through heat transfer primarily via conduction. Each platen 36 includes an integral heater (not shown) which is connected to a source of electrical power, such as through electrical conductors 40.

[0018] Particles 12 are simultaneously pressed together and heated above the melting point of the UHMWPE so that a net shaped articulating bearing surface 33 is formed. Heating the UHMWPE above its melting point allows free radicals in the UHMWPE formed during the crosslinking step to react with other free radicals in the UHMWPE, thereby forming a stable bond. The amount of time required during the forming process may take from a few minutes to several hours, depending upon whether the temperature of the UHMWPE is raised substantially above the melting point thereof, or is maintained at or slightly below the melting point thereof.

[0019] After the net shaped articulating bearing surface 33 is formed with compression mold 24, articulating bearing surface 33 is cooled and removed from within compression mold 24. A portion of articulating bearing surface 33 is machined using any suitable machining process to allow articulating bearing surface 33 to mate with an orthopaedic implant, such as tibial knee implant 42 shown in Fig. 3. For example, the portion of articulating bearing surface 33 on the bottom side of phantom line 44 (as viewed in Fig. 3) may be shaped and/or removed using a suitable machining process to allow articulating bearing surface 33 to mate with tibial knee implant 42. Of course, tibial knee implant 33 may be machined to define suitable keying and/or interlocking structures for interconnection with tibial knee implant 42.

[0020] In the embodiment shown, UHMWPE particles 12 are formed into articulating bearing surface 33 using compression mold 24. However, other suitable reforming methods may be used which apply heat and pressure, such as isostatic forming techniques, stamping, thermal forming, etc.

[0021] While this invention has been described as having a preferred design, the present invention can be

further modified within the spirit and scope of this disclosure. This application is therefore intended to cover any variations, uses, or adaptations of the invention using its general principles. Further, this application is intended to cover such departures from the present disclosure as come within known or customary practice in the art to which this invention pertains and which fall within the limits of the appended claims.

Claims

1. A method of manufacturing an articulating bearing surface for use in an orthopaedic implant, comprising the steps of:
 - providing a supply of ultra-high molecular weight polyethylene particles;
 - irradiating said particles with sufficient radiation energy to crosslink at least a portion of said ultra-high molecular weight polyethylene;
 - and
 - forming said irradiated particles into the articulating bearing surface.
2. The method of claim 1, wherein said forming step comprises the substeps of:
 - placing said irradiated particles into a mold;
 - pressing said irradiated particles within said mold; and
 - heating said particles within said mold.
3. The method of claim 2, wherein said block is heated above the melting point of said ultra-high molecular weight polyethylene.
4. The method of claim 2, wherein said mold comprises a compression mold.
5. The method of claim 1, wherein said particles comprise at least one of powder and flakes.
6. The method of claim 1, wherein said supply of particles comprises packets and said irradiating step comprises irradiating said particles within said packets.
7. The method of claim 6, wherein said supply of particles is formed by placing said packets of particles in a mold and pressing and heating the packet and particles within the mold.
8. The method of claim 1, wherein said irradiating step comprises irradiating said particles with sufficient radiation energy to crosslink substantially all of said ultra-high molecular weight polyethylene.
9. The method of claim 1, comprising the further step

of reducing an amount of oxygen in an ambient atmosphere around said particles during said irradiating step.

10. The method of claim 9, wherein said step of reducing the amount of oxygen within said reforming apparatus comprises bathing said particles in an inert gas.
11. The method of claim 1, wherein said radiation energy consists of one of gamma rays, X-rays, ultraviolet radiation, neutron particle beam, proton particle beam and electron particle beam.
12. The method of claim 1, wherein said articulating bearing surface is configured for use with a tibial knee implant.

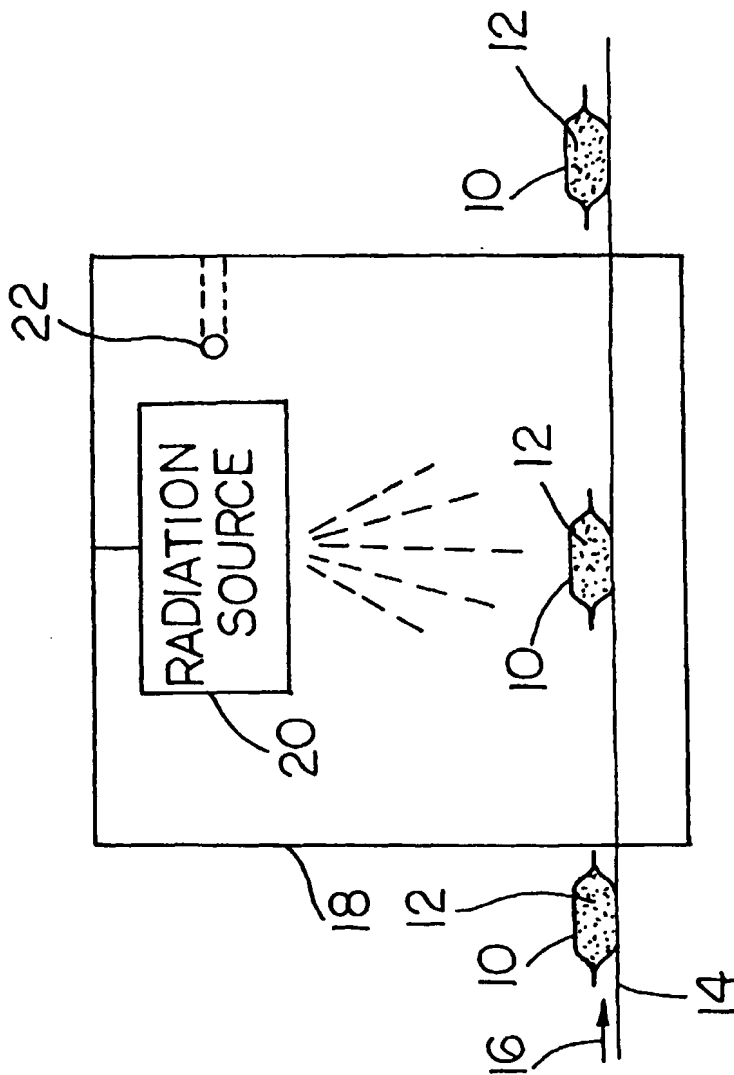


FIG. 1

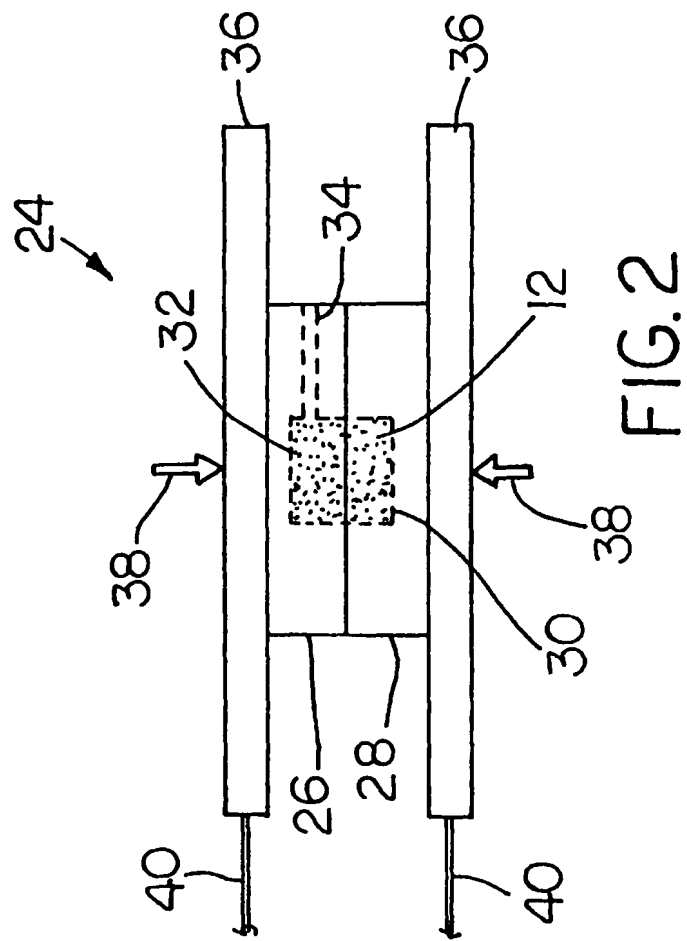
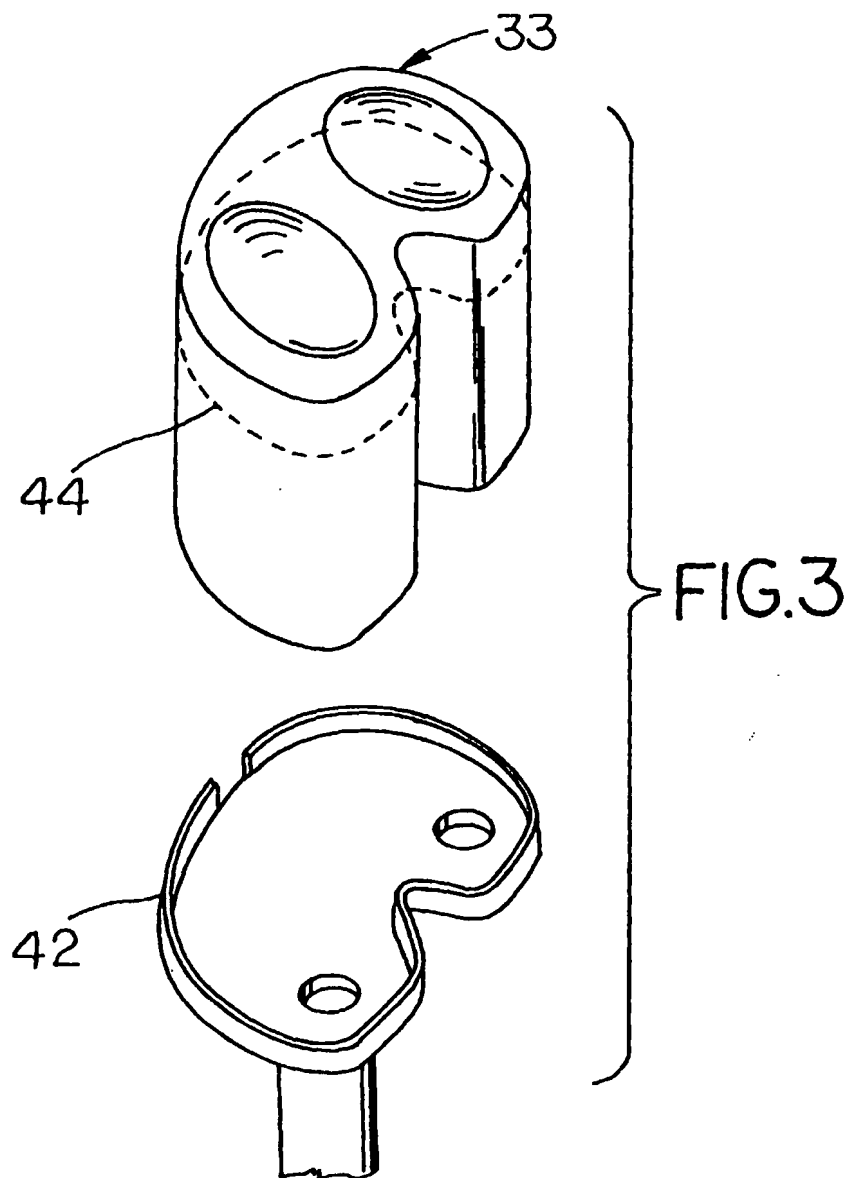


FIG. 2





European Patent
Office

EUROPEAN SEARCH REPORT

Application Number
EP 00 20 2677

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
X	WO 98 14223 A (DU PONT) 9 April 1998 (1998-04-09) * page 8, paragraph 3; claim 1 *	1	A61L27/16
X	WO 97 29793 A (GEN HOSPITAL CORP ;MASSACHUSETTS INST TECHNOLOGY (US)) 21 August 1997 (1997-08-21) * page 2, line 1 - page 3, line 19 *	1	
A	EP 0 722 973 A (ORTHOPAEDIC HOSPITAL ;UNIV SOUTHERN CALIFORNIA (US)) 24 July 1996 (1996-07-24) * abstract *	1	
A	EP 0 729 981 A (BMG INC) 4 September 1996 (1996-09-04) * abstract *	2	
A	US 5 543 471 A (SUN DEH-CHUAN ET AL) 6 August 1996 (1996-08-06) * abstract *	2	
			TECHNICAL FIELDS SEARCHED (Int.Cl.7)
			A61L
The present search report has been drawn up for all claims			
Place of search BERLIN		Date of completion of the search 17 November 2000	Examiner Korth, C-F
<p>CATEGORY OF CITED DOCUMENTS</p> <p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</p> <p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document</p>			

EPO FORM 1503 03.02 (P04001)

**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 00 20 2677

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

17-11-2000

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9814223	A	09-04-1998	US 6017975 A	25-01-2000
			AU 4742697 A	24-04-1998
			EP 0935474 A	18-08-1999

WO 9729793	A	21-08-1997	US 5879400 A	09-03-1999
			AU 2050697 A	02-09-1997
			CA 2246342 A	21-08-1997
			CN 1211195 A	17-03-1999
			CZ 9802490 A	14-04-1999
			EP 0881919 A	09-12-1998
			PL 328345 A	18-01-1999

EP 0722973	A	24-07-1996	AU 716762 B	09-03-2000
			AU 4078596 A	01-08-1996
			CA 2166450 A	21-07-1996
			IT T0960027 A	22-07-1996
			JP 9003207 A	07-01-1997

EP 0729981	A	04-09-1996	AU 693260 B	25-06-1998
			AU 3485595 A	09-04-1996
			CA 2177042 A	28-03-1996
			CN 1135762 A	13-11-1996
			WO 9609330 A	28-03-1996

US 5543471	A	06-08-1996	US 5414049 A	09-05-1995
			AT 171078 T	15-10-1998
			AT 196095 T	15-09-2000
			AU 684500 B	18-12-1997
			AU 6436494 A	20-12-1994
			DE 9490446 U	20-02-1997
			DE 69413395 D	22-10-1998
			DE 69413395 T	04-02-1999
			DE 69425838 D	12-10-2000
			EP 1005872 A	07-06-2000
			EP 0701453 A	20-03-1996
			EP 0847765 A	17-06-1998
			ES 2122260 T	16-12-1998
			WO 9427651 A	08-12-1994
			JP 2836965 B	14-12-1998
			JP 8509148 T	01-10-1996
			US 5449745 A	12-09-1995
			US 5650485 A	22-07-1997
			US 5728748 A	17-03-1998

EPO FORM P0489

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82